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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,127	02/19/2004	Kwang-wook Oh	KCL-0097	2678

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CANTOR COLBURN, LLP
20 Church Street
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Hartford, CT 06103

EXAMINER

BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1797

NOTIFICATION DATE	DELIVERY MODE
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08/21/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptopatentmail@cantorcolburn.com

Office Action Summary	Application No. 10/783,127	Applicant(s) OH ET AL.	
	Examiner WILLIAM H. BEISNER	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 3-5, 7-14 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6, 15, 17-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 6/9/2009 has been entered.

Election/Restrictions

2. Applicant's election of Group I, Species i), in the reply filed on 6/27/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 3-5, 7-14 and 16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and/or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/27/2007. Note, Applicants did not state which claims encompass the elected species. As a result, it is determined that claims 6 and 15 correspond to elected species i) while claims 1 and 2 are generic. Therefore, claims 1, 2, 6 and 15 will be examined on their merits.

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Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 2, 6, 15 and 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It appears that the sol-gel transformable material that functions as the microvalves in the instant claims is added to the device at the time of sample addition. It is not clear if this material is actually a structural component of the claimed device or merely material worked on by the device. For example material added to the device during use of the device and/or mixed with the sample during use. Clarification and/or correction is requested.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 6, 15 and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilding et al.(US 5,587,128).

With respect to claim 1, the reference of Wilding et al. discloses a PCR device (Figure 11) that includes an inlet (16A); an outlet (16D); a PCR channel (22A); a heat source (See

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column 24, lines 33-41). With respect to the recited microvalves and sol-gel material, the structure disclosed by the reference of Wilding et al. is structurally capable of being used with a sol-gel material positioned within the microchannels which function as microvalves. Note "Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim." *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969). Furthermore, "[i]nclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims." *In re Young*, 75 F.2d 996, 25 USPQ 69 (CCPA 1935) (as restated in *In re Otto*, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)) (See MPEP 2115).

With respect to claims 2 and 17-19, the structure of the device of Wilding et al. is structurally capable of being used with the material recited in claims 2 and 17-19.

With respect to claims 6 and 15, the reference of Wilding et al. include intersect portions (16B and 16C) which meet the structure of the claimed microvalves when containing a gel material.

8. Claims 1, 2 and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Mehta et al.(US 5,306,590).

With respect to claim 1, the reference of Mehta et al. (See Figure reproduced below) discloses a PCR device (Figure 3B) that includes an inlet; an outlet; a PCR channel; and a heat source (See column 15, lines 43-47 and column 17, lines 29-38).

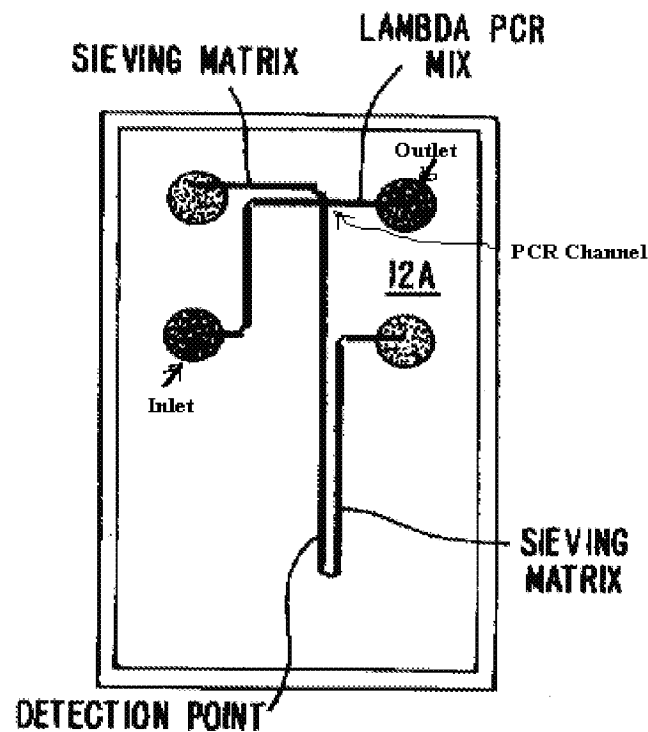


FIG. 3B.

With respect to the claimed first and second micro-valves and sol-gel transformable material, the reference discloses using a .5% methyl cellulose with the PCR reagents for use in the PCR channel positioned between the inlet and outlet (See Example 2). As a result, this mixture including methyl cellulose is considered to inherently meet the instantly claimed first and second micro-valves and sol-gel transformable material.

With respect to claims 2 and 17-19, the reference discloses the use of .5% methyl cellulose (See Example 2).

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9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

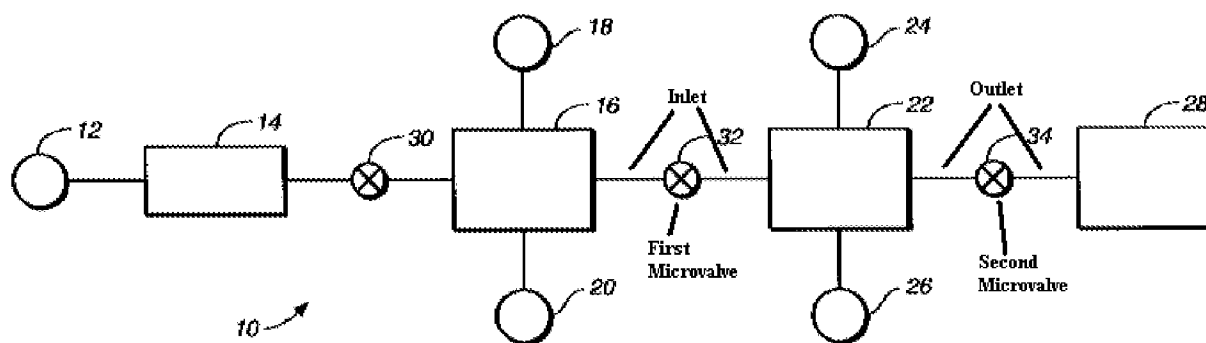
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1, 2, 6, 15 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blackburn (US 6,875,619) in view of Robotti et al.(US 2002/0054835).

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The reference of Blackburn discloses a PCR device (See Figure 8 reproduced hereafter) that includes an inlet ; an outlet; a PCR channel (22); a heat source (column 56, lines 39-41) for operating the PCR device; a first microvalve (32); and a second microvalve (34).



Claim 1 differs by reciting that the device includes a sol-gel transformable material, which transforms from a sol state into a gel state at a temperature lower than DNA denaturation temperature, annealing temperature and extension temperature and higher than room temperature.

The reference of Robotti et al. discloses that it is known in the art of microfluidic devices to employ thermoreversible polymeric gels as microvalves (See paragraphs [0032]-[0033]). The reference lists methyl cellulose as a known gel material.

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ thermoreversible gels in the system of the primary reference for the known and expected result of providing an alternative means recognized in the

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art to achieve the same result, control of the flow of fluids within a microfluidic device, and for the advantages discussed by the reference of Robotti et al. (See paragraph [0071]).

With respect to the temperature requirement of the gel of claims 1 and 17, the reference of Robotti et al. discloses the use of methyl cellulose which is disclosed in the instant specification as a material that meets this claim limitation (See instant claim 2). As a result, in the absence of further positively recited structure, the methyl cellulose of Robotti et al. is considered to have the same properties as that instantly claimed.

With respect to claim 2, the reference of Robotti et al. discloses the use of methyl cellulose (See paragraph [0033]).

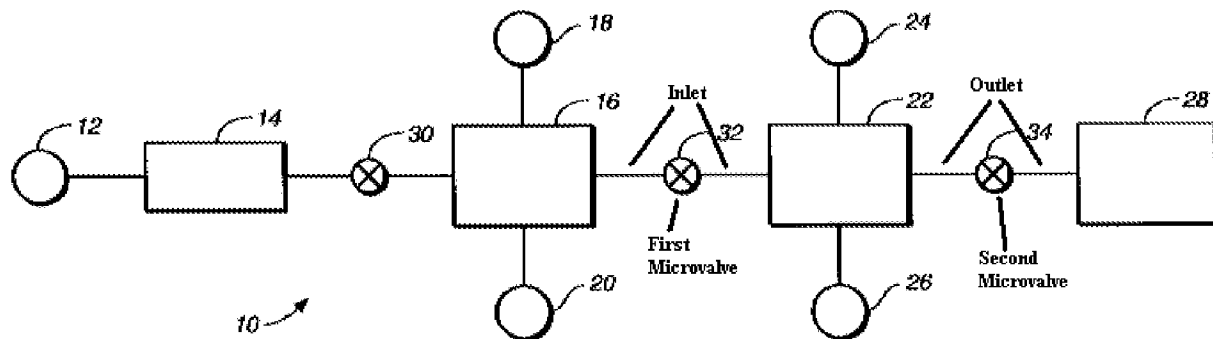
With respect to claims 6 and 15, the reference of Robotti et al. discloses that the valve structure can include intersecting flow paths wherein one of the flow paths is filled with the reversible material (See paragraph [0037]).

With respect to claims 18 and 19, in the absence of a showing of unexpected results, one of ordinary skill in the art would be capable of determining the optimum concentration of the methyl cellulose material based on considerations such as the method being performed in the device and/or the properties of the materials interacting with the methyl cellulose material while maintaining the required function of the valve devices.

13. Claims 1, 2, 6, 15 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blackburn (US 6,875,619) in view of Robotti et al.(US 2002/0054835) taken further in view of Yang et al.(US 6,382,254).

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The reference of Blackburn discloses a PCR device (See Figure 8 reproduced hereafter) that includes an inlet ; an outlet; a PCR channel (22); a heat source (column 56, lines 39-41) for operating the PCR device; a first microvalve (32); and a second microvalve (34).

**FIG. 8**

Claim 1 differs by reciting that the device includes a sol-gel transformable material, which transforms from a sol state into a gel state at a temperature lower than DNA denaturation temperature, annealing temperature and extension temperature and higher than room temperature.

The reference of Robotti et al. discloses that it is known in the art of microfluidic devices to employ thermoreversible polymeric gels as microvalves (See paragraphs [0032]-[0033]). The reference lists methyl cellulose as a known gel material.

The reference of Yang et al. discloses the use of thermoreversible polymeric gels as microvalves which meet the properties of the sol-gel transformable material of the instant claims (See column 3, lines 48-62).

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In view of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ thermoreversible gels in the system of the primary reference for the known and expected result of providing an alternative means recognized in the art to achieve the same result, control of the flow of fluids within a microfluidic device, and for the advantages discussed by the reference of Robotti et al. (See paragraph [0071]). The reference of Yang et al. also discloses the compatibility of the thermally-responsive material with biological material, including DNA (See column 3, lines 25-37).

With respect to the temperature requirement of the gel of claims 1 and 17, the references of Robotti et al. and Yang et al. disclose the use of methyl cellulose which is disclosed in the instant specification as a material that meets this claim limitation (See instant claim 2). As a result, in the absence of further positively recited structure, the methyl cellulose of Robotti et al. and/or Yang et al. is considered to have the same properties as that instantly claimed.

With respect to claim 2, the references of Robotti et al. and Yang et al. discloses the use of methyl cellulose (See paragraph [0033] of Robotti et al. and column 3, lines 57-62 of Yang et al.).

With respect to claims 6 and 15, the reference of Robotti et al. discloses that the valve structure can include intersecting flow paths wherein one of the flow paths is filled with the reversible material (See paragraph [0037]).

With respect to claims 18 and 19, in the absence of a showing of unexpected results, one of ordinary skill in the art would be capable of determining the optimum concentration of the methyl cellulose material based on considerations such as the method being performed in the

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device and/or the properties of the materials interacting with the methyl cellulose material while maintaining the required function of the valve devices.

Response to Arguments

14. Applicants' arguments filed 6/9/2009 are not found to be persuasive for the following reasons:

With respect to the combination of the reference of Blackburn and Robotti, Applicants argue that the combination is improper for the following reasons:

i) "Blackburn does not teach a valve having a gel than reversibly change its state to permit the valves to open and close" and "Blackburn further does not teach a sol-gel transformable material, which transforms from a sol state into a gel state at a temperature lower than DNA denaturation temperature, annealing temperature and extension temperature and higher than room temperature; as the temperature increases to operate the PCR by the heat source (See pages 8-9 of the response dated 6/9/2009).

ii) "Robotti does not teach that the channel disposed between micro-valves can be used for polymerase chain reaction" (See page 9 of the response dated 6/9/2009).

iii) "Robotti also does not teach a material that transforms from a sol state into a gel state at room temperature lower than DNA denaturation temperature, annealing temperature and extension temperature and higher than room temperature" (See page 9 of the response dated 6/9/2009).

iv) Robotti does not teach the methyl cellulose solution mixed with the PCR solution (See pages 9-10 of the response dated 6/9/2009).

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v) “One of ordinary skill in the art would not have combined Blackburn with Robotti because they teach away from each other. In particular, the channels sizes disclosed by Robotti are much larger than those disclosed by Blackburn” (See pages 10-13 of the response dated 6/9/2009).

vi) “Applicants further maintain that the Examiner has used an improper standard in arriving at the rejection of the above claims under section 103, based on improper hindsight” (See page 13 of the response dated 6/9/2009).

vii) Applicants further stress that the instant invention has several advantages over the prior art devices (See pages 13-14 of the response dated 6/9/2009).

In response to arguments i) and ii) above, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, it is the combination of the references that meets the limitations of the instant claims.

In response to argument iii) above, the reference of Robotti discloses that the gel material can be methyl cellulose which is the same material as that instantly claimed. As a result, the material disclosed by the reference of Robotti would have the same material properties as that of the instant invention and therefore inherently meets the claim language “a material that transforms from a sol state into a gel state at room temperature lower than DNA denaturation temperature, annealing temperature and extension temperature and higher than room temperature”.

In response to argument iv) above, it is noted that the features upon which applicant relies (i.e., methyl cellulose material mixed with the PCR solution) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Additionally, this argued feature also raises new issues with respect to the metes and bounds of the claimed device since the methyl cellulose solution is mixed with the PCR solution which would render the material as a “material worked on” and does not add further structure to the claimed device (See MPEP 2115).

In response to argument v) above, the Examiner does not agree with Applicants’ characterization of the references. It appears that Applicants are comparing the channel dimensions of the reference of Blackburn with the chamber dimensions of the reference of Robotti. One can clearly see from Figure 2 of Robotti that the valves (18) are associated with microchannels (14) rather than microchambers (17). Applicants’ characterization of the dimensions disclosed by Robotti are associated with microchambers (17) rather than microchannels (14). Paragraph [0024], last 11 lines, of Robotti clearly discloses that the maximum dimension of the microchannels should not exceed 250 microns which is of the same order as the microchannels of the reference of Blackburn (See pages 8-9 of Applicants' response dated 9/15/2008). In view of these disclosures, one of ordinary skill in the art would have readily recognized that the valves of the reference of Robotti could be used in the device of the reference of Blackburn. The Examiner also points to paragraph [0027] of Robotti which clearly suggests that the valves can be used in a variety of microfluidic devices.

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In response to argument vi) above, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In this case, it is the disclosures of the references of Blackburn and Robotti that suggest the combination and not the instant disclosure.

In response to argument vii) above, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Note that the instant claims do not preclude the presence of additional heat sources as part of the device.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM H. BEISNER whose telephone number is (571)272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/William H. Beisner/
Primary Examiner
Art Unit 1797**

WHB